CLAIM STATUS

Claim 2 was previously cancelled. Claims 3, 13, 15, and 19 were previously withdrawn.

Claims 1 and 20-22 are currently amended. Specifically, claims 1 and 20-22 are amended to clarify that the tissue graft or the multilayered tissue graft construct has a property of eversion upon placement in a blood vessel if not supported. Support for this amendment may be found throughout the specification, including at page 4, lines 3-8 and last paragraph continuing at page 5, lines 1-10; and at page 16, lines 3-6.

No new matter has been added.

Claims 1, 4-12, 14, and 16-18, and 20-22 are pending.

REMARKS

Rejection under 35 U.S.C § 103 – Obviousness

Summary

The Examiner issued a 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over U.S. Pat. No. 5,865,723 to Love (Love) in view of U.S. Pat. No. 5,891,193 to Robinson et al. (Robinson et al.) and further in view of U.S. Pat. No. 6,214,039 to Banas et al. (Banas et al.); rejection of claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and Banas et al. and further in view of U.S. Pat. No. 6,358,284 B1 to Fearnot et al. (Fearnot et al.); and rejection of claims 1, 12 and 16 as being unpatentable over U.S. Pat. No. 5,628,788 to Pinchuk (Pinchuk) in view of Fearnot et al. and further in view of Banas et al.

Applicants respectfully disagree with the Examiner's rejections for reasons described below.

At the outset, Applicants point out that, conventionally, stent grafts placed within the vascular system include one or more stents and graft material(s) affixed to the stents using, for example, sutures (Spec., page 3, last paragraph and continuing at page 4). There are different types of graft materials that may be used to form the stent grafts, including synthetic and biological graft materials. As required by Applicants' claims, the graft material that forms the device defined by Applicants' claims is a ***tissue***

graft, such as mature and juvenile small intestine submucosa (as opposed to a ***synthetic*** graft, such as Dacron or PET). As known in the art, the ***tissue*** grafts are not as strong and rigid as the ***synthetic*** types of the graft materials. In fact, the juvenile small intestine submucosa does not even have the density and strength of the mature small intestine submucosa and needs to be supported (Spec. at page 16, lines 3-6). In the devices defined by Applicants' claims, the tubular member is disposed over the ***tissue*** graft and around the stent and is ***retaining the tissue graft solely by compressive forces***. This type of configuration of the stent graft allows for support for the tissue graft, avoids any attachments sutures that can result in leakage of blood though the graft material, and prevents the ***tissue*** graft from everting or folding over on itself. Otherwise, simply covering a stent with a layer of ***tissue*** without any attachment thereto can result in the ***tissue*** material being pulled back or everted over itself when a delivery catheter is pulled back over the stent graft at the implantation site. The eversion creates a significant problem in that the aneurysm is no longer excluded and in that the stent graft with its everted tissue material presents a significant problem in its removal.

As amended claims 1, 2, 6, 9-11, 14, 17 and 18 are directed to stent ***tissue*** graft prostheses that include: (i) a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough, (ii) a ***tissue*** graft ***having the property of eversion upon placement in a blood vessel if not supported***, the tissue graft having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent, but not secured to said stent, and (iii) a tubular member having a distal tubular member end and a proximal tubular member end, a wall and a passage extending longitudinally therethrough, the tubular member being disposed over said tissue graft and around said first stent and retaining said tissue graft disposed on said first stent solely by compressive forces. In a pre-implantation configuration, a most distal end of the first distal stent end is at least coincident with a most distal end of the distal tissue graft end and a most proximal end of the first proximal stent end is at least coincident with a most proximal end of the proximal tissue graft end. During implantation and post-implantation of the prosthesis, the most distal tissue graft end and the most proximal tissue graft end remain

substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first expandable stent. The distal and the proximal tubular member ends are substantially coincident with the respective distal and proximal first stent ends.

The amended independent claim 20 also is directed to a stent ***tissue*** graft prosthesis and differs from claim 1 by inclusion of a multilayered ***tissue*** graft construct.

Claims 21 and 22 are also generally directed to stent ***tissue*** graft prostheses. However, in clams 21 and 22, in a pre-implantation configuration, the most distal end of the first distal stent end of the prostheses *extends beyond* the most distal end of the distal ***tissue*** graft end (claim 21) or the multilayered ***tissue*** graft construct end (claim 22) and the most proximal end of the first proximal stent end of the prostheses *extends beyond* a most proximal end of the proximal ***tissue*** graft end (claim 21) or multilayered ***tissue*** graft construct end (claim 22) and where during implantation and post-implantation of the prosthesis, the most distal ***tissue*** graft end (claim 21) or the multilayered ***tissue*** graft construct end (claim 22) and the most proximal ***tissue*** graft end (claim 21) or multilayered ***tissue*** graft construct end (claim 22) remain substantially in the pre-implantation configuration such that the ***tissue*** graft (claim 21) or the multilayered ***tissue*** graft construct (claim 22) does not evert or fold into the passage of the first expandable stent.

Argument for Claims 1, 6, 9-11, 14, 17, 18 and 20-22

The Examiner rejected claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al. and further in view of Banas et al. Specifically, the Examiner asserted that although Love does not disclose that the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft, Robinson et al. teach an inner expandable stent member having anchors that extend beyond the graft distal and proximal ends. The Examiner further asserted that although Love does not teach that the tissue graft is held by the tubular member solely by compressive forces, "Banas [et al.] teaches use of implant comprising a stent and a graft that retains their positioning during and after implantation without adhesives or sutures, solely by compressive forces

..." (Office action at page 3, lines 5-8). The Examiner concluded that it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Love to have stent anchor extensions that extend beyond the graft ends as taught by Robinson et al. and to eliminate the use of adhesives in light of compressive forces as taught by Banas et al.

The rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 under 35 USC § 103(a) is respectfully traversed. Applicants point out that the Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. § 103 as a basis for rejection of these claims. The applied Love, Robinson et al., and Banas et al. references, alone or in combination, do not teach or suggest each and every element of Applicants' claims 1, 6, 9-11, 14, 17, 18 and 20-22. There is also no suggestion, motivation or any reason to modify the teachings of Love, Robinson et al., and Banas et al. to provide the stent ***tissue*** graft prostheses as claimed.

MPEP 2142 states that "[to] establish a *prima facie* case of obviousness ... the prior art reference ... must teach or suggest all the claim limitations." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Love fails to teach, either expressly or inherently, each and every element recited in rejected independent claims 1 and 20-22 and provides no teaching, suggestion, or any reason as to the desirability of modifying the stent ***tissue*** graft prostheses described therein to include each and every element of the rejected independent claims 1 and 20-22. Specifically, Love does not teach invention of claims 1 and 20-22, because Love does not teach stent ***tissue*** graft prostheses that include either a ***tissue*** graft ***having the property of eversion upon placement in a blood vessel if not supported***, the tissue graft having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent, but not secured to said stent (claims 1 and 21) or a multilayered ***tissue*** graft construct ***having the property of eversion upon placement in a blood vessel if not supported***, the multilayered tissue graft construct having a distal construct end and a proximal construct end, a tubular wall and a passage extending longitudinally therethrough and disposed on said first stent (claims 20 and 22). Also, as already pointed out by the Examiner, "Love does not disclose that the

distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft or that the implant is held together ... solely by compressive forces" (Final Office action dated December 22, 2008, at page 2, last paragraph).

The Examiner cited Robinson et al. and Banas et al. to purportedly overcome the deficiencies of Love. However, neither Robinson et al. nor Banas et al. cure the deficiencies of Love because neither of the secondary references cited by the Examiner teach whatsoever stent ***tissue*** graft prostheses that include a ***tissue*** graft ***having the property of eversion upon placement in a blood vessel if not supported.***

Next, the Examiner argues that would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Love according to teachings of Robinson et al. and Banas et al. to arrive at Applicants' invention of claims 1, 6, 9-11, 14, 17, 18 and 20-22. However, there would have been absolutely no motivation or reason to modify the cited Love reference in order to arrive at the claimed stent ***tissue*** graft prostheses inasmuch as the applied Love, Robinson et al. and Banas et al. references never even acknowledge or recognize that stent ***tissue*** graft prostheses can include either a ***tissue*** graft ***having the property of eversion upon placement in a blood vessel if not supported*** (claims 1 and 21), or a multilayered ***tissue*** graft construct ***having the property of eversion upon placement in a blood vessel if not supported***. In addition, the applied Love, Robinson et al. and Banas et al. references never acknowledge or recognize that stent ***tissue*** graft prostheses, in a pre-implantation configuration, a most distal end of the first distal stent end is ***at least coincident*** with a most distal end of the distal ***tissue*** graft end and a most proximal end of the first proximal stent end is ***at least coincident*** with a most proximal end of the proximal ***tissue*** graft end and where during implantation and post-implantation of the prosthesis, the most distal ***tissue*** graft end and the most proximal ***tissue*** graft end remain substantially in the pre-implantation configuration such that the ***tissue*** graft ***does not evert or fold into the passage of the first expandable stent***. The teachings are only found in Applicants' disclosure and, in accordance with MPEP 2143, cannot provide the basis for a motivation to modify a reference.

Applicants' invention of claims 1, 6, 9-11, 14, 17, 18 and 20-22 would not have been obvious in view of the Love, Robinson et al. and Banas et al. references. Consequently, Applicants request that the 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al. and further in view of Banas et al. be withdrawn.

Argument for Claims 4, 5, 7 and 8

The Examiner rejected claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and Banas et al. and further in view of Fearnot et al.

As discussed above, because (1) the Love reference does not teach Applicants' invention, (2) the Robinson et al. and Banas et al. references do not cure the deficiencies of Love, and (3) one of ordinary skill in the art would not have a reason to modify the prosthesis of Love to include a ***tissue*** graft ***having the property of eversion upon placement in a blood vessel if not supported***, and note that, in a pre-implantation configuration, a most distal end of the first distal stent end is at least coincident with a most distal end of the distal ***tissue*** graft end and a most proximal end of the first proximal stent end is at least coincident with a most proximal end of the proximal ***tissue*** graft end and where during implantation and post-implantation of the prosthesis, the most distal ***tissue*** graft end and the most proximal ***tissue*** graft end remain substantially in the pre-implantation configuration such that the ***tissue*** graft ***does not evert or fold into the passage of the first expandable stent***, the invention of independent claim 1 would not have been obvious.

Furthermore, the Fearnot et al. reference does not provide a reason to modify the prosthesis of Love to arrive at a stent ***tissue*** graft prosthesis that includes a ***tissue*** graft ***having the property of eversion upon placement in a blood vessel if not supported***. Although Fearnot et al. disclose that the graft may be a multi-layer graft construct that includes purified submucosa, Fearnot et al. require that the graft be "an easy-to-produce and **mechanically strong** tube of an implantable graft" (Abstract, line 1; emphasis added) and asserts that "[t]he necessary characteristics of a tubular vascular prosthesis are biological compatibility, adequate **strength**, resistance to infection, ..." (column 2, lines 12-14; emphasis added). As such, Fearnot et al. teach

away from Applicants' inventions of claims 4, 5, 7 and 8 that require the presence of ***tissue*** graft that is flimsy and ***has the property of eversion upon placement in a blood vessel if not supported***.

Because the stent tissue graft prosthesis of Applicants' claim 1 is both novel and non-obvious, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 4, 5, 7 and 8 are not obvious under 35 U.S.C. §103 over Love in view of Robinson et al. and further in view of Fearnot et al. Applicants request that the obviousness rejection of claims 4, 5, 7 and 8 be withdrawn.

Argument for Claims 1, 12 and 16

The Examiner rejected claims 1, 12 and 16 as being unpatentable over Pinchuk in view of Fearnot et al. and further in view of Banas et al. Specifically, the Examiner asserted that "Pinchuk discloses invention substantially as claimed being a double-layered stent graft wherein the inner stent is smaller than the outer stent and the ends of each layer are at least coincident as seen in figures 3-9 [of Pinchuk]" (Office action dated December 22, 2008, page 4, lines 8-10). The Examiner further asserts that although the Pinchuk reference does not teach that the graft can comprise multiple layers of tissues or that the elements of the prosthesis can be held together solely by compressive forces, 1)"Fearnot teaches the use of tubular grafts comprising layers of submucosa tissue sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues" (Office action, page 4, lines 13-15), and 2) "Banas et al. teaches use of an implant comprising a stent and a graft that retains their positioning during and after implantation without adhesive or sutures, solely by compressive forces in the same field of endeavor for the purpose of eliminating the use of adhesives" (Office action, page 4, lines 16-19). The Examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot et al. with the double layered stent graft of Pinchuk and to eliminate the use of adhesives in light of compressive forces as taught by Banas et al. in order to provide enhanced repair of diseased host tissues and better anchoring and expansion and to better anchor the

implant vessel without the use of glue" (Office action at page 4, lines 20-22, and continuing at page 5, lines 1-3).

The rejection of claims 1, 12 and 16 under 35 USC § 103(a) is respectfully traversed. Applicants point out that the Examiner has not established a *prima facie* case of obviousness under 35 U.S.C. § 103 as a basis for rejection of these claims. The applied Pinchuk, Fearnot et al., and Banas et al. references, alone or in combination, do not teach or suggest each and every element of Applicants' claims 1, 12 and 16. There is also no suggestion, motivation or any reason to modify the teachings of Pinchuk, Robinson et al., and Banas et al. to provide the stent ***tissue*** graft prostheses as claimed.

MPEP 2142 states that "[to] establish a *prima facie* case of obviousness ... the prior art reference ... must teach or suggest all the claim limitations." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Neither the text of the specification nor the figures, including figures 3-9, of the Pinchuk reference teach or show stent ***tissue*** graft prostheses that include a ***tissue*** graft ***having the property of eversion upon placement in a blood vessel if not supported***, the ***tissue*** graft having a distal tissue graft end and a proximal tissue graft end and disposed on a first stent, but not secured to the stent. Also, neither the text of the specification nor the figures, including figures 3-9, of the Pinchuk reference teach or show stent ***tissue*** graft prostheses that include, in a pre-implantation configuration, a ***first (inner) stent with ends that are at least coincident with the ends of a tissue graft***, where during implantation and post-implantation of the prosthesis, the most distal tissue graft end and the most proximal tissue graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first expandable stent. Moreover, neither the text nor the figures of Pinchuk teach that ***the distal and the proximal tubular member ends are substantially coincident with the respective distal and proximal first stent ends***.

Specifically, Pinchuk does not teach or suggest using ***tissue*** graft to form a stent ***tissue*** graft prosthesis, as claimed by Applicants. Rather, Pinchuk teaches that a ***textile*** tube can be used as the graft material. Specifically, at column 5, lines 1-2 and

other instances throughout the cited reference, Pinchuk states "[t]he ***textile*** tube 22 is preferably a warp-knit or atlas-knit of ***PET*** fibers" (emphasis added). Clearly, synthetic graft materials are not the same as biological graft materials, such as tissue graft materials and are handled differently.

Also, regarding the Examiner's assertion that "Pinchuk discloses invention substantially as claimed being a double-layered stent graft wherein the inner stent is smaller than the outer stent and the ends of each layer are at least coincident as seen in figures 3-9 [of Pinchuk]" (Office action dated December 22, 2008, page 4, lines 8-10), Applicants point out that none of figures 3-9 of Pinchuk actually illustrate stent ***tissue*** graft prostheses where ***both***, ***the proximal and distal ends of the inner stent are coincident with the ends of the tissue graft*** such that the tissue graft does not evert or fold into the passage of the first expandable stent, as required by Applicants' claims. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)[1].

[1] Applicants' arguments presented at pages 10-13 of Amendment and Response filed on April 25, 2007 together with a request for continued examination and after issuance of final Office action dated March 12, 2007, arguments presented at pages 11-14 of Response to the Office action dated February 19, 2008, and arguments presented at pages 13-17 of Amendment and Response dated September 24, 2008, are incorporated herein by reference.

Specifically, figures 3-6 do not illustrate Applicants' prostheses. Rather, figures 3 and 4 of Pinchuk, as copied for Examiner's convenience below, illustrate a graft (***textile*** tube) and figures 5 and 6 illustrate a stent graft; i.e., stent-over-graft).

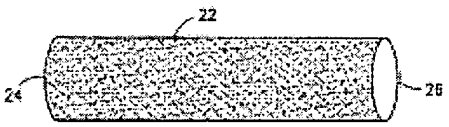


FIG. 3

GRAFT

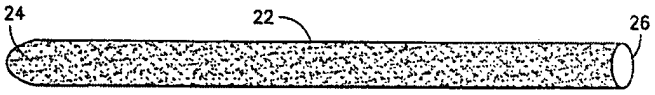


FIG. 4

GRAFT

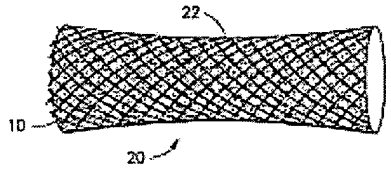


FIG. 5

STENT-OVER-GRAFT

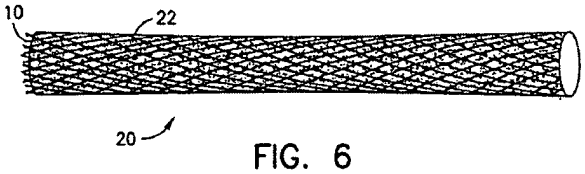


FIG. 6

STENT-OVER-GRAFT

It is clear that none of the figures 3-6 of Pinchuk show a ***two***-stent device with ***tissue*** graft in-between. An inner stent is missing from figures 3-6 of Pinchuk. As such, the proximal and distal ends of the ***inner*** stent can not be coincident with the ends of the tissue graft simply because ***the inner stent is not taught*** in figures 3-6 of Pinchuk.

Similarly, figures 3-6 of Pinchuk do not illustrate that the distal and the proximal tubular member ends are substantially coincident with the respective distal and proximal ***first*** stent ends because the ***first (i.e., inner) stent in absent from these figures***.

Furthermore, figures 7-9 of Pinchuk, which are copied for the Examiner's convenience below, do not show Applicants' invention. Rather, figures 7-9 of Pinchuk are cross-sectional views of various exemplary stent graft configurations and illustrate only small *portions* of the actual devices. Because there is no specific teaching in the text of the specification of Pinchuk that the ends of the inner stent 10 at least coincide with the ends of the graft 22, and figures 7-9 illustrate only small *portions* of the actual devices (rather than entire device), one of skill in the art would not conclude that figures

7-9 of the Pinchuk reference teach or suggest ends of the *inner* stent coinciding with the ends of the graft or suggest the distal and the proximal tubular member ends being substantially coincident with the respective distal and proximal first stent ends.

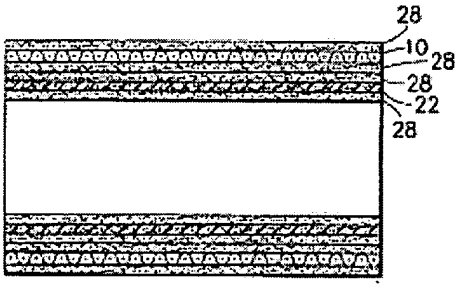


FIG. 7

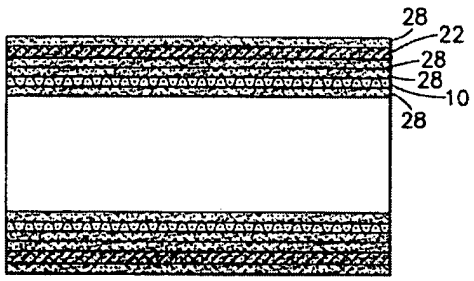


FIG. 8

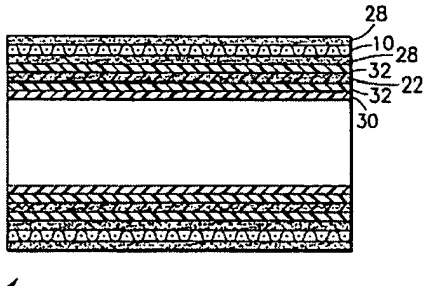


FIG. 9

Although, the Pinchuk reference states that the inner stent may be included with the devices of some other figures, there is no teaching or suggestion whatsoever in the Pinchuk reference of ends of the ***inner stent*** being ***at least coincident with the ends of the tissue graft***. Clearly there is no teaching or suggestion whatsoever in the Pinchuk reference of all the elements of Applicants' claims 1, 12, and 16.

The Examiner cited Fearnot et al. and Banas et al. to purportedly overcome the deficiencies of Pinchuk. However, neither Fearnot et al. nor Banas et al. cure the deficiencies of Pinchuk because neither of these references teach or suggest whatsoever stent ***tissue*** graft prostheses that include a ***tissue*** graft ***having the property of eversion upon placement in a blood vessel if not supported***.

In fact, Fearnot et al. teach away from Applicants' invention because Fearnot et al. require that the graft be "an easy-to-produce and **mechanically strong** tube of an implantable graft " (Abstract, line 1; emphasis added) and asserts that "[t]he necessary

characteristics of a tubular vascular prosthesis are biological compatibility, adequate **strength**, resistance to infection, ..." (column 2, lines 12-14; emphasis added). In contrast, Applicants claims require the presence of a ***tissue graft*** that is flimsy and ***has the property of eversion upon placement in a blood vessel if not supported***.

Furthermore, nothing in Fearnot et al. suggests modifying the prosthesis of Pinchuk to include ***an inner stent with ends that are at least coincident with the ends of a tissue graft*** so that during implantation and post-implantation of the prosthesis, the most distal tissue graft end and the most proximal tissue graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first expandable stent, and so that the distal and the proximal tubular member ends are substantially coincident with the respective distal and proximal first stent ends.

In view of the above remarks, it would not have been obvious to one of skill in the art to combine the Pinchuk, Fearnot et al., and Banas et al. references to arrive at the invention of claim 1. Because the stent tissue graft prosthesis of Applicants' claims 1 is both novel and non-obvious, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 12 and 16 are not obvious under 35 U.S.C. §103 over Pinchuk in view of Fearnot et al. and Banas et al. Accordingly, Applicants request that the obviousness rejection of claims 1, 12 and 16 be withdrawn.

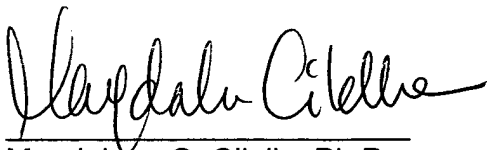
Conclusion

For the foregoing reasons, Applicants request that the 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al. and further in view of Banas et al.; rejection of claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and Banas et al. and further in view of Fearnot et al.; and rejection of claims 1, 12 and 16 as being unpatentable over Pinchuk in view of Fearnot et al. and Banas et al. be withdrawn.

SUMMARY

Applicants respectfully submit that the present application is now in condition for allowance. If, for any reason, the Examiner feels a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,



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